

Country: Singapore: Standards and Conformity Assessment

Chia Swee Hoon Feb 2008

Singapore: Standards and Conformity Assessment - General Overview

This market research report is one of a series produced by the U.S. Commercial Service with practical information for U.S. companies about standards and conformity assessment issues affecting U.S. exporters in specific sectors, to improve their ability to access foreign markets. Existing standards-related market research such as the Country Commercial Guide standards sections offers a good introduction to the major standards and conformity assessment institutions. These reports build on this information by delving into conformity assessment procedures as they pertain to specific sectors in specific national markets.

I. General Overview

The following report was prepared to address the latest trends in conformity assessment in Singapore. Specific focus has been given to the following sectors: telecommunications equipment, computer hardware and software, medical equipment, cosmetics and toiletries, and aircraft and parts.

In Singapore, compliance to Singapore Standards is voluntary. However, they become mandatory when used by government bodies in regulations or administrative requirements for safety, environmental and health issues. All Singapore Standards are reviewed once every five years to consider whether they should be confirmed, revised, amended, archived or withdrawn. However if the need arises, Singapore Standards may be reviewed before the five-year period. Requests for the development or review of a standard may come from the public, industry, academia or government. Singapore has signed a number of multilateral mutual recognition arrangements (MRAs/MLAs).

II. Main Bodies

Singapore's national standardization program is administered by SPRING Singapore, the national standards authority. It establishes and publishes Singapore Standards, by notification in the Government Gazette. The Standardization Division in SPRING Singapore represents Singapore in regional and international standards activities and promotes the alignment of national standards to international standards.

SPRING Singapore coordinates the Singapore Standardization Program under the guidance of an industry-led national Standards Council, which comprises representatives from the private and public sectors. The Standards Council formulates the strategies and direction for the standardization program. All standardization work is carried out by the standards partners, with the Standardization Division providing secretariat support to the Council and its various standards committees as well as technical committees and working groups appointed to draft standards.

Besides being the national standards authority in Singapore, SPRING is also the national accreditation body. SPRING manages the Singapore Accreditation Council (SAC). SAC's primary function is to accredit conformity assessment bodies based on international standards. Accreditation is an endorsement of an organization's competence, credibility, independence and integrity in carrying out its conformity

assessment activities. This endorsement is manifested in the use of the SAC mark of accreditation when it accredits an organization or on test reports and calibration.

SPRING Singapore is the country's representative to the International Organization for Standardization (ISO). SPRING has been actively involved in both the policy and technical levels of the ISO. Singapore is also a member of the International Electrotechnical Commission (IEC) through the Singapore National Committee of the IEC.

SPRING Singapore represents Singapore's interest in regional standards and conformance by participating actively in regional standardization such as in the Asia Pacific Economic Cooperation (APEC) Sub-Committee on Standards & Conformance (SCSC), the ASEAN Consultative Committee for Standards & Quality (ACCSQ) and the Pacific Area Standards Congress (PASC).

III. Product Certification Process

The Consumer Protection (Safety Requirements) Regulations 2002 mandates that 45 categories of electrical, electronics and gas home appliances and accessories be registered before they can be advertised, traded or displayed for sale in Singapore. They include adaptors, LPG systems, cooking ranges, electric irons, gas cookers, hair dryers, microwave ovens, televisions, video display units, video cassette recorders, table fans, high-fidelity equipment, immersion water heaters, kettles, refrigerators, rice cookers, room air-conditioners, vacuum cleaners and washing machines. SPRING has registered more than 40,000 models of controlled goods. More information is available on the website: www.spring.gov.sg/safety.

Singapore is part of the ASEAN Economic area, and as part of it, mutual recognition agreements (MRA) become effective for compulsory standards of certain electrical products traded between Thailand, Malaysia and Singapore. Eligible products for MRA must meet the IEC or its equivalent standards.

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Singapore: Standards and Conformity Assessment –Telecommunications Equipment

This market research report is one of a series produced by the U.S. Commercial Service with practical information for U.S. companies about standards and conformity assessment issues affecting U.S. exporters in specific sectors, to improve their ability to access foreign markets. Existing standards-related market research such as the Country Commercial Guide standards sections offers a good introduction to the major standards and conformity assessment institutions. This report builds on the information by delving into conformity assessment procedures as they pertain to the telecommunications equipment sector in Singapore.

I. Overview

Singapore is one of the most wired countries in the world. In December 2007, mobile phone penetration hit 122.5% and household broadband penetration rate reached 79.2%. There are more than 6,200 public Wi-Fi hotspots island wide, which means there are more than 22 wireless LAN hotspots for every square mile of the country. Singapore has a well developed network of fiber optics cables that span the country. 'Cyber cafes' are popular, and Internet connections are available in most hotels. 3.5G networks based on the High-Speed Downlink Packet Access (HSDPA) standard as well as Worldwide Interoperability for Microwave Acces (WiMAX) networks are being progressively deployed in the country. With total submarine cable capacity of 28 Tbps³ and direct international Internet connectivity of 25 Gbps³, Singapore is well positioned as a hub for international capacity as well as a transcable hub where regional submarine cable systems and international cable systems interconnect.

Singapore is a sophisticated market for telecommunications products and services. There are excellent opportunities to sell new applications and solutions to the country and through Singapore as it is a leading adopter in the region and a major entrepot. Best prospects include equipment, content, software and technologies for broadband, wireless broadband, 3G, and Mobile TV.

II. Main Bodies

The Infocomm Development Authority of Singapore (IDA) formulates and develops short and mediumterm infocomm-related policies, as well as standards, codes of practices and advisory guidelines pertaining to the telecom industry.

III. Product Certification Process

The IDA regulates the use of telecommunication equipment based on Technical Specifications published by IDA. A Technical Specification is a Standard that prescribes the minimum technical requirements to be fulfilled by telecommunication equipment intended for sale and use in Singapore. IDA also publishes Reference Specifications which describe the network and network-to-network interface (NNI) standards adopted or yet to be adopted by operators in Singapore. Consistent with the policy of technological neutrality, these NNI standards are for general information of or reference by operators, equipment suppliers and the public. The IDA regulates the performance of key services offered by operators by setting Quality of Service (QoS) standards and requiring the operators to submit periodic reports of their service quality. More information can be found at http://www.ida.gov.sg/Policies%20and%20Regulation/20060419202223.aspx

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Singapore: Standards and Conformity Assessment – Computer

This market research report is one of a series produced by the U.S. Commercial Service with practical information for U.S. companies about standards and conformity assessment issues affecting U.S. exporters in specific sectors, to improve their ability to access foreign markets. Existing standards-related market research such as the Country Commercial Guide standards sections offers a good introduction to the major standards and conformity assessment institutions. This report builds on the information by delving into conformity assessment procedures as they pertain to the computer sector in Singapore.

Overview

Singapore is a mature and sophisticated market for IT products and services. According to the 2006 survey carried out by the Infocomm Development Authority (IDA) of Singapore, 77% of Singaporean households owned at least one home computer and almost 9 in 10 households with school-going children had access to a home computer. Seventy-one percent of households had home Internet access and in these homes, almost all (97%) used computers as the mode of access while 9% used Internet-enabled cell phones. Usage of computers was 100% in businesses with more than 250 employees but the usage level declined to 62% for companies with fewer than 10 employees. Usage of infocomm network technologies was similarly higher for larger companies. Details on infocomm usage in households and by individuals as well as businesses can be found at http://www.ida.gov.sg/Publications/20061205092557.aspx

Singapore's domestic market for computer hardware and software amounted to US\$3.7 billion in 2006, according to the latest IDA's Annual Survey on the Infocomm Industry for 2006. Details of the survey can be found at

http://www.ida.gov.sg/doc/Publications/Publications Level2/20061205092557/ASInfocommIndustry06.pdf

II. Main Bodies

Nil.

III. Product Certification Process

There is currently no product certification for computer hardware of software products in Singapore.

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Singapore: Standards and Conformity Assessment – Medical Equipment

This market research report is one of a series produced by the U.S. Commercial Service with practical information for U.S. companies about standards and conformity assessment issues affecting U.S. exporters in specific sectors, to improve their ability to access foreign markets. Existing standards-related market research such as the Country Commercial Guide standards sections offers a good introduction to the major standards and conformity assessment institutions. This report builds on the information by delving into conformity assessment procedures as they pertain to the medical equipment sector in Singapore.

Overview

Singapore's healthcare services are comparable to those of other industrialized economies. The government spends approximately 3.8% of GDP annually on healthcare.

In 2006, U.S. exports of medical equipment and supplies to Singapore registered a healthy increase of approximately 30% from 2005, with total imports from the United States at US\$327 million. This was due to the economic recovery in Singapore and the region. There was also a corresponding increase in total imports though imports from the United States rose more significantly, with the United States capturing a 24% market share. Based on available trade figures for 2007 and market expectations for 2008, U.S. export of medical equipment to Singapore is expected to again register an increase. Overall, the regional economies have been steadily improving and thriving, and this is expected to translate into more transshipments through Singapore as the island-state is viewed as a major trade hub and launching pad into the region.

The Singapore Parliament passed the Health Products Act in February 2007 and medical devices was the first health product group to be regulated under the Act. Singapore's Health Sciences Authority (HSA), through its Centre for Medical Devices Regulation (CMDR), will oversee the system of statutory control aimed to safeguard the quality, safety and efficacy of medical devices available in Singapore. By 2010, all medical devices – from high-risk stents for heart surgery to low-risk ones like mechanical wheelchairs - will need to be licensed. The control measures will keep pace with global trends and standards and the agency will take into consideration the regulatory decisions of benchmark agencies like those of the U.S. Food & Drug Administration, the U.K. Medicines Control Agency, Therapeutic Goods Administration of Australia and the European Agency for the Evaluation of Medicinal Products.

The Singapore government is focused on moving up the value chain through the provision of services that assist research and healthcare delivery in Singapore and the region. Over the next few years, it will pump nearly a billion dollars into the biomedical sciences sector with the aim to boost health-care standards and clinical research capabilities. The challenge is to develop 'bench to bedside' research that will see the fruits of this work making its way into mainstream medicine and benefit all Singaporeans. The government's vision is to develop Singapore as the Healthcare Services Hub in Asia and projects that its share of this growing market will expand to 3% by 2012, achieving one million healthcare visitors per year. Singapore is also emphasizing caring for an aging population, living a healthy lifestyle with a focus on preventive care, and doing a better job of tackling chronic illnesses. U.S. firms with revolutionary or cutting-edge medical technology or focus on health screening and disease management would find Singapore an ideal place to launch their products.

II. Main Bodies

The Health Sciences Authority (HSA) is a multidisciplinary agency in health sciences expertise. Its core capabilities encompass administering the national regulatory frameworks for pharmaceuticals, complementary medicines, medical devices and other health products; the running of the national blood

bank and provision of transfusion medicine services; and the provision of forensic medicine expertise, investigative forensic and analytical science services.

The HSA's Center for Medical Device Regulation (CMDR) is entrusted with the responsibility of regulating medical device products placed on the Singapore market. Its objective is to safeguard public health and safety by implementing regulatory controls through a program of pre-market assessment of devices, manufacturing controls and post-market vigilance. CMDR also administers the Contact Lens Practitioners Act through the registration and licensing of Contact Lens Practitioners and the enforcement of the Act and its regulations

III. Product Certification Process

Since April 1, 2002, the CMDR carries out a range of assessment and monitoring activities to ensure medical equipment available in Singapore are of an acceptable standard under a Voluntary Product Registration scheme. With the passage of the Health Products Act 2007 in February 2007, HSA is implementing the Health Products (Medical Devices) Regulations to better regulate medical devices in Singapore in three phases:

Phase 1 Implementation

Since November 1, 2007, the following duties and obligations were imposed on medical device dealers. Medical device dealers must:

- -Report adverse events to HSA within stipulated time frame
- -Notify HSA prior to the initiation of a product recall
- -Keep records of complaints and product distribution

The false or misleading advertisements and promotions of medical devices was prohibited. HSA can direct an advertiser to publish a "corrective advertisement" for any false or misleading advertisements.

Phase 2 Implementation

From April 1, 2008, HSA will start accepting applications for licensing of dealers of medical devices and registration of medical device products.

Phase 3 Implementation

The last phase of the implementation will be conducted in 2 stages:

From October 1, 2009:

- Unlicensed manufacturing, importation and wholesaling of medical device is prohibited.
- Supply of unregistered Class B, C, and D medical devices is prohibited

From October 1, 2010:

Supply of unregistered Class A medical devices is prohibited.

Updates and details can be found at

http://www.hsa.gov.sg/publish/hsaportal/en/health_products_regulation/medical_devices.html

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Singapore: Standards and Conformity Assessment – Cosmetics

This market research report is one of a series produced by the U.S. Commercial Service with practical information for U.S. companies about standards and conformity assessment issues affecting U.S. exporters in specific sectors, to improve their ability to access foreign markets. Existing standards-related market research such as the Country Commercial Guide standards sections offers a good introduction to the major standards and conformity assessment institutions. This report builds on the information by delving into conformity assessment procedures as they pertain to the cosmetics sector in Singapore.

Overview

According to estimates provided by industry sources, the cosmetics and toiletries retail sector in Singapore is worth approximately US\$400 million in 2007. The economy has rebounded significantly in the last two years and the general sentiment among the population is a positive one. Based on statistics from the Singapore Department of Statistics, overall retail sales (excluding motor vehicles) rose by 6% in May 2007 over May 2006.

The domestic retail market is sophisticated with various market segments, from those with high disposable income who seek premium and high-quality products, to mass-market consumers who are more price-sensitive. Besides the affluent, local resident population, Singapore is also home to over one million foreigners, with a significant expatriate population that enjoy a high-quality lifestyle.

Singapore is also viewed as a springboard into the fast-growing South East Asian market and serves as a showcase for the neighboring countries. U.S. companies seeking to expand into the region should consider using Singapore to launch and showcase their products and services. For the cosmetics and toiletries sector, more than 80% of all imports are re-exported, making Singapore an ideal gateway into the region.

II. Main Bodies

The controlling authority for the regulation and licensing of cosmetic products use is the Health Sciences Authority, Ministry of Health. The Cosmetics Control Unit (CCU), which was set up in November 1995, is responsible for the administration of the regulations for cosmetic products.

III. Product Certification Process

Effective January 1, 2008, the HSA implemented the ASEAN Cosmetic Directive (ACD) under the Health Products Act for the regulatory control of cosmetic products. The new subsidiary legislation "Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations 2007" supersedes the previous legislation governing the control of cosmetic products under the Medicines Act. Please click on the following link to download The Health Products (Cosmetic Product - ASEAN Cosmetic Directive) Regulations 2007. Please click on the following link to download the Guidelines on the Control of Cosmetic Products.

ASEAN Cosmetic Directive (ACD)

The ACD is the result of an ASEAN-wide initiative to harmonize the regulation of cosmetic products through a set of standardized requirements that safeguards public health and safety. All member countries are obliged to implement the ACD by January 1, 2008. HSA views the ACD as an opportunity for greater collaboration in ASEAN. For more information on the ACD, please click here

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Singapore: Standards and Conformity Assessment – Aircraft and parts

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Overview

Singapore leads the rest of Asia in aircraft maintenance, engine repair, component repair and overhaul capabilities. It is well placed to maintain its leadership position to capture a larger slice of the \$40.8 billion global commercial maintenance repair and overhaul (MRO) market, which is expected to grow at 3.6% a year to \$58 billion over the next 10 years.

Singapore's MRO sector had an output of \$4.5 billion and employed some 18,000 workers in 2006. Independent and airline MRO operators accounted for about 36% of revenue, while original equipment manufactures (OEMs) took up 34%. In terms of activities, engine overhaul is the single biggest segment, accounting for 48% of the total revenue and component repair accounted for 26%.

By 2018, Singapore's aerospace output is expected to double to \$9.0 billion, according to projections by the Singapore Economic Development Board. This growth will be fuelled, among other factors, by the expansion of low-cost carriers that typically outsource to cut costs, and the arrival of new aircraft such as the Boeing 787 and Airbus 380 needing new maintenance and support equipment and expertise that airlines may not want to invest in.

II. Main Bodies

The Civil Aviation Authority of Singapore (CAAS), which is a statutory body under the Ministry of Transport is responsible for the Civil Aviation standards and conformity assessment in the country. In the execution of its functions, CAAS is backed by prescribed powers and also by national law such as the Civil Aviation Authority of Singapore Act (and subsidiary legislation thereunder), Air Navigation Act (and subsidiary legislation thereunder), Carriage By Air Act, Tokyo Convention Act, Hijacking of Aircraft and Protection of Aircraft and International Airports Act.

The Civil Aviation Authority of Singapore Act, in particular, spells out the functions of CAAS, which include the following:

- (a) to maintain and manage the CAAS' aerodrome and to provide such services and facilities as are necessary or expedient for its operations;
- (b) to provide air traffic control service, flight information service, alerting service and aeronautical information service within the Singapore Flight Information Region;
- (c) to regulate and to promote the development of air transport; and
- (d) to act internationally as the national authority or body representing Singapore in respect of matters relating to civil aviation.

The Air Navigation Act and the subsidiary legislation thereunder (eg. the Air Navigation Order and the Air Navigation (Aviation Security) Order) gives effect to the Convention on International Civil Aviation ("Chicago Convention") and its 18 Annexes, all of which contain the Standards and Recommended Practices adopted in accordance with the Chicago Convention.

III. **Product Certification Process**

Singapore signed technical arrangements on aviation maintenance with Hong Kong and Canada. It also signed a bilateral aviation safety agreement (BASA) with the United States in February 2004 (Executive Agreement) and September 2007 (Implementation procedures for air worthiness). The BASA covers design and manufacturing of TSO and STC products and enables design, manufacture and direct shipment of aerospace systems from the U.S. to Singapore and vice versa. CAAS will accept products certified by FAA and vice versa. Technical Standard Order (TSO) is a minimum standard for specified materials, parts and appliances used on civil aircraft. Supplementary Type Certificate (STC) is a type certificate issued when an applicant has received FAA approval to modify an aircraft from its original design.

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